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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,289	01/02/2004	Syed F.A. Hossainy	50623.363	2385

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EXAMINER

HAGOPIAN, CASEY SHEA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/751,289

Applicant(s)

HOSSAINY ET AL.

Examiner

Casey Hagopian

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-66 is/are pending in the application.
4a) Of the above claim(s) 37-64 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 65 and 66 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/29/05.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Receipt is acknowledged of applicant's Information Disclosure Statement filed 8/29/2005 and Amendment/Remarks filed 10/21/2005.

Election/Restrictions

2. Newly amended claim 37 and its dependent claim 41 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the reservoir region of claims 37 and 41 as originally written comprised a drug whereas the newly amended claims includes a reservoir region comprising a drug and a polymer. In the Restriction Requirement dated 12/30/2004, the examiner had presented separate groups including elected Group II (claim 41) drawn to a device comprising a reservoir region comprising a drug and non-elected Group IX (claim 53) drawn to a device comprising a reservoir region comprising a drug and a polymer. Therefore, the newly amended claims 37 and 41 are no longer directed to the original elected invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 37 and 41 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

MAINTAINED REJECTIONS

3. Claims 37 and 41 have been withdrawn for the reasons set forth in the above paragraph 2, however newly added claims 65 and 66 are added to the original rejection under 35 USC 102.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 65 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Ragheb et al. (USPN 5,824,049). Ragheb discloses a coated implantable medical device comprising a primer layer, a drug layer, and a porous layer, wherein the primer layer is posited onto the surface of the medical device (abstract; figure 1; column 11, lines 1-5). It should be noted that the examiner is interpreting the drug layer and porous layer together as a reservoir region. The instant claim only defines the reservoir region as comprising a drug and the instant specification states, "a coating having a reservoir region carrying an active agent" (page 5, line 19) and "the primer and reservoir regions can be made from the same polymeric material or different polymeric materials" (page 5, line 25 – page 6, line1). It is unclear how the drug and polymer interact within the reservoir region. Ragheb also discloses polymers including photopolymerizable polyethylenically unsaturated acrylic esters containing two or more acrylate groups per molecule such as trimethylopropane triacrylate (column 11, lines 21-39). Ragheb's

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disclosure of polymers including photopolymerizable polyethylenically unsaturated acrylic esters containing two or more acrylate groups per molecule also reads on polyester diacrylates. Therefore, the disclosures of Ragheb render the claim anticipated.

Response to Arguments

6. Applicant's arguments, see page 10, filed 10/21/2005, with respect to the objection of claim 41 have been fully considered and are persuasive. The objection of claim 41 has been withdrawn.

7. Applicant's arguments filed 10/21/2005 regarding the rejection under 35 USC 102 have been fully considered but they are not persuasive. Applicant argues that:

a. Ragheb does not teach a reservoir region comprising a drug and a polymer, and

b. The particular Ragheb example of monomer, trimethylopropane triacrylate, forms a saturated polymer without any acrylate groups.

8. In regards to argument a, the examiner finds the argument moot in view of the addition of non-elected subject matter as explained in paragraph 2 of the rejection.

9. In regards to argument b, the examiner agrees with applicant's assertion that for the particular monomer trimethylopropane triacrylate when it is combined with another monomer, the acrylates would fall out and leave a saturated backbone. However, column 11 of Ragheb includes other examples (i.e. ethylene glycol diacrylate) that would not necessarily have the same effect. Also, Ragheb's disclosure of

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polyethylenically unsaturated acrylic esters read on polyester diacrylates. For these reasons, the rejection has been maintained.

NEW REJECTIONS

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 65 and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claim 65 includes a Markush group comprising polyisocyanates, unsaturated polymers, high amine content polymers, acrylates, polymer containing a high content of hydrogen bonding groups, inorganic polymers and any combination thereof. The Markush group contains species that overlap, for instance acrylates and high amine content polymers are included in unsaturated polymers and inorganic polymers include a number of possibilities. Therefore, the Markush group is improper and indefinite. Clarification/correction is requested.

13. Claim 66 includes a Markush group comprising polyester diacrylates, polycaprolactone diacrylates, polytetramethylene glycol diacrylate, polyacrylates with at least two acrylate groups, polyacrylated polyurethanes, triacrylates, and any combination thereof. The specific species "polyacrylates with at least two acrylate groups" is unclear. Is applicant referring to diacrylates and/or triacrylates? If this is the

case, the Markush group already includes triacrylates, polyester diacrylates, and so on. The Markush group is vague and indefinite. Clarification/correction is requested.

Conclusion

14. All claims have been rejected; no claims are allowed.
15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on M-F from 8:00 am to 5:00 pm.

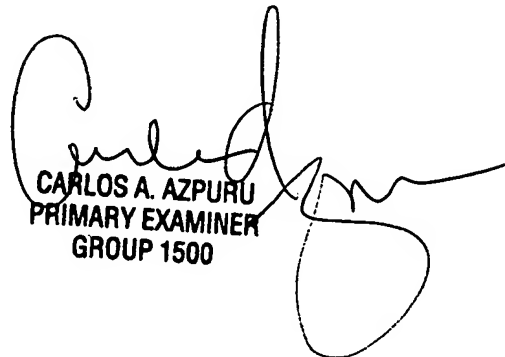
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Casey Hagopian
Examiner
Art Unit 1615



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